



4. Attached as Exhibit C is a copy of an electronic printout of the press release issued by Forest on January 24, 2002 announcing that it had received an “approvable” letter from FDA for LEXAPRO.

5. Attached as Exhibit D is a copy of the FDA approval letter for LEXAPRO for the treatment of major depressive disorder dated August 14, 2002.

6. As reported in Forest’s 2003 10-K, filed with the Securities and Exchange Commission (“SEC”) on June 27, 2003, sales of LEXAPRO during fiscal 2003 were \$244,730,000. The 10-K further reported that, according to data published by IMS, an independent prescription audit firm, as of June 13, 2003, LEXAPRO achieved a 12.1% share of total prescriptions for antidepressants in the selective serotonin reuptake inhibitor/selective norepinephrine reuptake inhibitor (“SSRI/SNRI”) category. Attached as Exhibit E are copies of selected pages from an electronic printout of Forest’s 2003 10-K.

7. Attached as Exhibit F is a copy of the FDA approval letter for LEXAPRO for the treatment of general anxiety disorder (“GAD”) dated December 18, 2003.

8. As reported in Forest’s 2004 10-K, filed with the SEC on June 14, 2004, sales of LEXAPRO during fiscal 2004 were \$1,088,957,000. The 10-K further reported that, according to IMS data, as of May 21, 2004, LEXAPRO achieved a 16.7% share of total prescriptions for antidepressants in the SSRI/SNRI category. Attached as Exhibit G are copies of selected pages from an electronic printout of Forest’s 2004 10-K.

9. As reported in Forest’s 2005 10-K, filed with the SEC on June 14, 2005, sales of LEXAPRO during fiscal 2005 were \$1,605,296,000. The 10-K further reported that, according to IMS data, as of April 30, 2005, LEXAPRO achieved a 19.9% share of

total prescriptions for antidepressants in the SSRI/SNRI category. Attached as Exhibit H are copies of selected pages from an electronic printout of Forest's 2005 10-K.

10. As reported in Forest's 2006 10-K, filed with the SEC on June 14, 2007, sales of LEXAPRO during fiscal 2006 were \$1,873,255,000. The 10-K further reported that, according to IMS data, as of April 30, 2006, LEXAPRO achieved a 20.1% share of total prescriptions for antidepressants in the SSRI/SNRI category. Attached as Exhibit I are copies of selected pages from an electronic printout of Forest's 2006 10-K.

11. As reported in Forest's 2007 10-K, filed with the SEC on May 30, 2007, sales of LEXAPRO during fiscal 2007 were \$2,105,990,000. The 10-K further reported that, according to IMS data, as of April 30, 2007, LEXAPRO achieved an 18.5% share of total prescriptions for antidepressants in the SSRI/SNRI category. Attached as Exhibit J are copies of selected pages from an electronic printout of Forest's 2007 10-K.

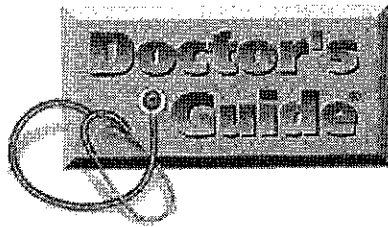
12. On August 28, 2007, I typed "lexipro" into the Google search engine. Attached as Exhibit K are electronic printouts that show a selected portion of search results.

13. Attached as Exhibit L is an electronic printout of the website at <http://depression.emedtv.com/lexapro/lexipro.html>, the first link presented by Google as a result of my search for "lexipro."

Dated: August 28, 2007  
New York, New York

  
\_\_\_\_\_  
ERIC M. AGOVINO

# **EXHIBIT A**



## Medical & Other News

To print: Select File and then Print from your browser's menu

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### Title: **Escitalopram, New Generation Selective Serotonin Reuptake Inhibitor, Promising In Major Depressive Disorder**

URL: <http://www.pslgroup.com/dg/1ED81A.htm>

Doctor's Guide

December 13, 2000

SAN JUAN, PUERTO RICO -- December 13, 2000 -- Escitalopram, the isomer of Celexa™ (citalopram HBr) and a new generation selective serotonin reuptake inhibitor (SSRI), produced significant improvement relative to placebo at 10 mg/day and 20 mg/day doses in a Phase III clinical trial of 366 patients with major depressive disorder, reported researchers here at the American College of Neuropsychopharmacology 2000 Annual Meeting in San Juan, Puerto Rico.

Based on the clinical trial data, Forest Laboratories will submit a New Drug Application in the first half of 2001 to the U.S. Food and Drug Administration seeking an indication for escitalopram for the treatment of depression.

"Escitalopram exhibited strong efficacy at doses of 10 and 20 mg/day, which is noteworthy because no other anti-depressant is approved as effective in a general population of depressed patients at 10 mg/day," noted William Burke, MD, professor of psychiatry, University of Nebraska Medical Center and lead investigator of the escitalopram clinical trial. "The drug was well-tolerated at both daily dosages."

Citalopram is a racemic mixture with two mirror image halves, an S- and R-isomer. The S-isomer of citalopram is the active isomer in terms of its contribution to citalopram's antidepressant effects, while the R-isomer does not contribute to its antidepressant activity. With escitalopram, the R-isomer has been removed, leaving only the active S-isomer or single isomer.

In a double-blind, multicenter clinical trial, a total of 366 patients with an ongoing major depressive episode were randomized to placebo, escitalopram 10 mg/day, or escitalopram 20 mg/day and entered an eight-week double-blind treatment period. Patients in the 20 mg/day escitalopram group were titrated to their assigned dose after one week of treatment at a dose of 10 mg/day.

Both escitalopram 10 mg/day and escitalopram 20 mg/day produced significant improvement compared to placebo on all of the depression measures by the study's end. Severity of depression symptoms was evaluated with the Montgomery Asberg Depression Rating Scale (MADRS), the Hamilton Depression Rating Scale (HAMD) and the Clinical Global Impressions (CGI) scale. Significant improvement versus placebo was observed beginning at week 1 on the CGI Improvement scale and the HAMD depressed mood item and from week 2 onwards on the MADRS and HAMD. Once the significant improvement was established in week one or two, it was maintained throughout the study period.

"The magnitude of change from baseline to the study's end in the Hamilton Depression Rating Scale or HAMD was especially impressive," noted Dr. Burke.

Treatment with escitalopram in the Phase III clinical trial was well tolerated: the incidence of discontinuations for adverse events was 2.5 percent in the placebo group, 4.2 percent in the escitalopram 10 mg/day group, and 10.4 percent in the escitalopram 20 mg/day group. "Escitalopram had remarkably low discontinuance rates in our study due to its high tolerability," noted Dr. Burke.

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# **EXHIBIT B**

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## Results of Escitalopram and Celexa(TM) Studies Presented at Major Scientific Conference

### FOREST LABORATORIES LOGO

Forest Laboratories Inc. Logo. (PRNewsFoto)[AG]  
 NEW YORK, NY USA

Forest Laboratories, Inc.

NEW YORK, Dec. 13 /PRNewswire/ -- Forest Laboratories, Inc. (NYSE: **FRX**) announced that clinical study results were presented today at an annual meeting of neuropsychopharmacologists, including a trial demonstrating that escitalopram helps prevent the relapse of depressive episodes when used as maintenance therapy. Other research presented at the meeting included: a pooled analysis of flexible-dose studies demonstrating that patients with major depressive disorder treated with either escitalopram or Celexa(TM) (citalopram HBr) showed significantly greater improvement than patients receiving placebo, and a study demonstrating that Celexa may significantly reduce depression in adolescents and children.

(Photo: <http://www.newscom.com/cgi-bin/prnh/20001011/FORESTLOGO> )

Celexa, a selective serotonin reuptake inhibitor (SSRI) for the treatment of depression marketed by Forest Laboratories, is the fastest growing SSRI in the United States. Escitalopram, a single isomer derived from Celexa, is an investigational SSRI for depression and other disorders. Forest submitted a New Drug Application for escitalopram to the U.S. Food and Drug Administration earlier this year. Escitalopram will be marketed by Forest Laboratories in the U.S. under the trade name Lexapro(TM).

"Forest is committed to the development of effective medications for the treatment of depression, and the results of these studies are especially encouraging," said Howard Solomon, chairman and chief executive officer, Forest Laboratories.

### Escitalopram and Prevention of Relapse

In a study of patients with major depressive disorder aged 18 to 81 years, fewer patients treated with escitalopram relapsed and their time to relapse was significantly longer than those receiving placebo. The risk of relapse was shown to be 44 percent lower in patients treated with escitalopram than in those treated with placebo. Escitalopram-treated patients also exhibited significantly fewer symptoms of depression during the double-blind phase than those patients who received placebo.

"Individuals with depression face the possibility of relapsing and experiencing another depressive episode, even after achieving initial success with antidepressant treatment," said Mark Rapaport, M.D., associate professor at the University of California San Diego School of Medicine and the study's lead investigator. "This study demonstrates that escitalopram can effectively reduce the risk of relapse after an initial response to treatment, allowing people with depression to lead more productive lives."

The study began with an initial eight-week, flexible-dose, open-label treatment phase with escitalopram. Escitalopram was flexibly dosed between 10 mg and 20 mg per day during this open-label phase. Patients who were classified as responders were then randomly assigned to 36 weeks of double-blind, fixed-dose treatment. Of the 274 patients in the fixed-dose treatment phase, 181 patients received escitalopram, and 93 patients received placebo. Patients received the same dose of escitalopram during the fixed-dose phase as they had received at the end of the open-label phase. The primary efficacy variable was time to depression relapse from the start of the



double-blind treatment phase.

#### Pooled Analysis of Flexible-Dose Studies

A pooled analysis of two earlier randomized, double-blind, flexible-dose, placebo-controlled studies with a total of 844 patients showed that patients with major depressive disorder who were treated with either escitalopram or Celexa showed significantly greater improvement than depressed patients receiving placebo. Dosing of escitalopram and Celexa was adjusted as needed at specified intervals during the eight-week studies. Escitalopram was dosed at 10 mg or 20 mg per day, with a mean daily dose of 12.6 mg throughout the studies; Celexa was dosed at either 20 mg or 40 mg per day with a mean daily dose of 25.5 mg throughout the studies. The analysis showed that escitalopram and Celexa were both statistically superior to placebo on all efficacy measures. However, this superiority was demonstrated by escitalopram in the first week of treatment and later in the study by Celexa.

In both studies, escitalopram was well tolerated, with some patients experiencing adverse events including headache, nausea, diarrhea, and insomnia. Similar to previously reported studies, escitalopram discontinuation rates due to adverse events were comparable to placebo.

#### Celexa in the Treatment of Pediatric Depression

Celexa was shown to reduce symptoms of depression in adolescents and children with major depressive disorder to a significantly greater extent than placebo in a randomized, double-blind, placebo-controlled, flexible-dose study of 174 pediatric patients (83 children and 91 adolescents). Thirty-six percent of patients treated with Celexa for eight weeks demonstrated a reduction in depressive symptoms compared to 24 percent in the placebo group. Symptoms of depression in the Celexa group began to decrease significantly in the first week of the study and continued to decrease throughout the study. The study also showed that Celexa was well tolerated. The primary outcome measure was the Children's Depression Rating Scale-Revised (CDRS-R), a standard diagnostic tool.

"This study is significant because few studies involving any antidepressant have shown efficacy compared to placebo in the treatment of depression in children and adolescents," said Karen Dineen Wagner, MD, PhD, Department of Psychiatry and Behavioral Sciences, University of Texas Medical Branch at Galveston, and the study's lead author. "Citalopram is now one of the few therapies for which we have data showing safety and efficacy for this population."

Children in the study were 7 to 11 years old, and adolescents 12 to 17 years old. All patients in the treatment arm were given 20 mg per day of Celexa at the start of the study. Investigators had the option to increase the dose to 40 mg per day any time after the fourth week. The mean daily dose of Celexa in the final week of the study was 23.3 mg for children and 24.4 mg for adolescents. The rate of discontinuation due to adverse events was comparable in the Celexa and placebo groups (5.6 percent vs. 5.9 percent), suggesting that Celexa doses of 20 to 40 mg per day were well tolerated by the children and adolescents in the study. The more common side effects associated with use of Celexa were nausea, influenza-like symptoms, and rhinitis.

Celexa is indicated for the treatment of depression in adults over the age of 18. Currently, there are no therapies approved for the treatment of major depressive disorders in the pediatric population. The American Academy of Child and Adolescent Psychiatry estimates that 5 percent of the pediatric population -- or 3.4 million children and adolescents under the age of 18 -- suffer from depression.

About Celexa

Celexa is currently indicated for the treatment of depression in adults aged 18 and older. Prescribed for more than six million U.S. patients, Celexa is the fastest growing antidepressant in the U.S. Celexa is marketed by Forest Laboratories in the U.S. Celexa has been well tolerated by patients in many large-scale clinical trials. The most frequent side effects reported were nausea, dry mouth, drowsiness, insomnia, increased sweating, tremor, diarrhea, and problems with ejaculation. Full prescribing information can be found on the Internet at <http://www.celexa.com>.

#### About Escitalopram: An Isomer of Celexa

Escitalopram is the product of a relatively new research approach that involves the removal of one of two isomers from Celexa to create a single-isomer drug. Celexa is a racemic mixture with two mirror-image halves called the S- and R-isomers. The S-isomer of Celexa (escitalopram) is the highly selective active isomer in terms of its contribution to Celexa's antidepressant effects. With escitalopram, the R-isomer (that does not contribute to Celexa's antidepressant activity) has been removed, leaving only the therapeutically active S-isomer. Moreover, isolation of escitalopram (the S-isomer) eliminates any unwanted pharmacological effects associated with Celexa's R-isomer. In three efficacy trials involving more than 1,100 patients, escitalopram was very well tolerated at doses of 10 and 20 mg per day. Escitalopram dropout rates due to adverse events were comparable to placebo in all three studies.

#### About Forest Laboratories and Its Products

Forest Laboratories (NYSE: **FRX**) develops, manufactures, and sells ethical pharmaceutical products that are used for the treatment of a wide range of illnesses. Forest Laboratories' growing line of products includes: Tiazac(R) (diltiazem HCL), a once-daily treatment for angina and hypertension; and Aerobid(R) (flunisolide), an inhaled steroid indicated for the treatment of asthma. Besides escitalopram for the treatment of depression and other disorders, products in Forest's development pipeline include: memantine for Alzheimer's disease and neuropathic pain, lercanidipine for hypertension, acamprosate for alcohol dependence, ML3000 for osteoarthritis, dexloxiglumide for irritable bowel syndrome, neramexane for various central nervous system disorders, siramesine for anxiety, and ALX-0646 for migraine headache.

The Danish pharmaceutical firm H. Lundbeck A/S developed both citalopram and escitalopram.

Except for the historical information contained herein, this release contains forward looking statements that involve a number of risks and uncertainties, including the difficulty of predicting FDA approvals, acceptance and demand for new pharmaceutical products, the impact of competitive products and pricing, the timely development and launch of new products, and the risk factors listed from time to time in the Company's SEC reports, including the Company's Annual Report on Form 10-K for the fiscal year ended March 31, 2001 and the quarterly report on Form 10-Q for the periods ended June 30, 2001 and September 2001.

SOURCE Forest Laboratories, Inc.

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**Related links:**

- <http://www.celexa.com>

**Photo Notes:**<http://www.newscom.com/cgi-bin/prnh/20001011/FORESTLOGO>

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## Press release

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### **Lexapro(TM), The Single-Isomer of Celexa(TM), Receives FDA Approvable Letter**

NEW YORK, Jan. 24 /PRNewswire-FirstCall/ -- Forest Laboratories, Inc. (NYSE: FRX) announced today that it has received an approvable letter from the United States Food and Drug Administration (FDA) for Lexapro(TM) (escitalopram oxalate). Lexapro, the single-isomer of Celexa(TM) (citalopram HBr), is being developed by Forest Laboratories for the treatment of major depressive disorder. An approvable letter represents the final stage before a company receives FDA clearance to market the product in the United States. Forest expects to launch Lexapro in mid-2002 subject to final FDA approval.

Forest filed a New Drug Application (NDA) for Lexapro, a selective serotonin reuptake inhibitor (SSRI), in March 2001. The NDA was based on a fixed dose trial of Lexapro compared to placebo and Celexa. Forest and Lundbeck (Forest's licensor of Lexapro) have conducted several multi-center, placebo-controlled clinical trials involving more than 1,300 patients with moderate to severe depression. In the trials, Lexapro was shown to be well tolerated and to significantly improve symptoms of depression in the first or second week of treatment. The most frequent adverse events observed in these trials were nausea, insomnia and ejaculation disorder. In fixed dose studies, the overall incidence rates of adverse events in patients treated with Lexapro 10 mg daily was similar to that in placebo treated patients.

"We are very pleased to receive an approvable notification from the FDA," said Howard Solomon, Chairman and Chief Executive Officer of Forest Laboratories. "The approvable letter does not raise any clinical issues with respect to Lexapro and we expect to be able to adequately respond to the letter and agree to final labeling."

Lexapro is the product of a relatively new research approach that involves the removal of one of two isomers from Celexa to create a single-isomer drug. Celexa is a racemic mixture made up of equal amounts of two mirror-image molecules called the S- and R-isomers. The S-isomer of Celexa (Lexapro) is the active isomer in terms of its contribution to Celexa's antidepressant effects. With Lexapro, the R-isomer (that does not contribute to Celexa's antidepressant activity) has been removed, leaving only the therapeutically active S-isomer. Moreover, isolation of Lexapro (the S-isomer) eliminates any potential unwanted effects associated with Celexa's R-isomer.

In the United States, approximately 19 million adults suffer from depression each year. It is estimated that one in four American women and one in ten American men can expect to develop depression during their lifetime.

#### Studies in Other Indications

Forest Laboratories also stated that it was pleased with the results of initial placebo controlled Lexapro clinical trials in Generalized Anxiety Disorder, Panic Disorder and Social Anxiety Disorder. Results of those studies are expected to be reported in March at the Anxiety Disorders Association of America annual meeting.

#### About Forest Laboratories and Its Products

Forest Laboratories develops, manufactures, and sells ethical pharmaceutical products that are used for the treatment of a wide range of illnesses.

Forest Laboratories' growing line of products includes: Celexa(TM), which has been prescribed for more than six million U.S. patients and is the fastest growing antidepressant in the U.S.; Tiazac(R), a once-daily diltiazem, which is indicated for the treatment of angina and hypertension; and Aerobid(R), an inhaled steroid indicated for the treatment of asthma.

Other products in Forest's development pipeline include: memantine for Alzheimer's disease and neuropathic pain, lercanidipine for hypertension, acamprosate for alcohol dependence, ML3000 for osteoarthritis, dexloxiglumide for irritable bowel syndrome, neramexane for various central nervous system disorders, siramesine for anxiety, Aerospa(R) for asthma, and ALX-0646 for migraine headache.

Except for the historical information contained herein, this release contains forward-looking statements that involve a number of risks and uncertainties, including the difficulty of predicting FDA approvals, acceptance and demand for new pharmaceutical products, the impact of competitive products and pricing, the timely development and launch of new products, and the risk factors listed from time to time in the Company's SEC reports, including the Company's Annual Report on Form 10-K for the fiscal year ended March 31, 2001 and the quarterly reports on Form 10-Q for the periods ended June 30, 2001 and September 30, 2001.

**Source:** Forest Laboratories, Inc.

**Website:** <http://www.frx.com>

**Photo Notes:** <http://www.newscom.com/cgi-bin/prnh/20001011/FORSTLOGO>

**Contact:** Charles E. Triano

Vice President-Investor Relations of Forest Laboratories, Inc.

+1-212-224-6714/

[Charles.Triano@frx.com](mailto:Charles.Triano@frx.com)

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# **EXHIBIT D**





DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

NDA 21-323

Forest Laboratories, Inc.  
Attention: Robert W. Ashworth, Ph.D.  
Senior Director, Regulatory Affairs  
Plaza 3, Suite 602  
Harborside Financial Center  
Jersey City, NJ 07311

Dear Dr. Ashworth:

Please refer to your new drug application (NDA) dated March 23, 2001, received March 23, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lexapro (escitalopram oxalate) 5 mg, 10 mg, and 20 mg Tablets.

We acknowledge receipt of your submission dated February 28, 2002. Your submission of February 28, 2002 constituted a complete response to our January 23, 2002 action letter.

This new drug application provides for the use of Lexapro for the treatment of major depressive disorder.

We have completed the review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the enclosed labeling text. Accordingly, the application is approved effective on the date of this letter.

We note your agreement to the attached labeling in an e-mail communication dated August 14, 2002.

Additionally, we note your agreement, conveyed in your February 28, 2002 resubmission, to adopt the following dissolution method and specification for all strengths of the Lexapro (escitalopram oxalate) 5 mg, 10 mg, and 20 mg Tablets:

Apparatus:	USP Apparatus 2 (Paddle)
Paddle Speed:	50 RPM
Medium:	900 mL 0.1N HCL at 37°C
Specification:	NLT (b)(in 30 minutes

We also refer to your fax transmission on August 5, 2002, in which you provided additional ECG information for escitalopram. In particular, we reference your analysis of plasma concentration and change from baseline in QTc interval in study MD-01. We ask that you provide, postapproval, a more complete report on your analysis, including a listing of individual plasma concentrations and the corresponding values for change from baseline in

NDA 21-323

Page 2

QTc interval.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved NDA 21-323." Approval of this submission by FDA is not required before the labeling is used.

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, Maryland 20857

Please submit one market package of the drug product when it is available.

If you have any questions, call Paul David, R.Ph., Senior Regulatory Project Manager, at (301) 594-5530.

Sincerely,

*{See appended electronic signature page}*

Russell Katz, M.D.  
Director  
Division of Neuropharmacological Drug Products  
Office of Drug Evaluation I  
Center for Drug Evaluation and Research

Attachment

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**This is a representation of an electronic record that was signed electronically and  
this page is the manifestation of the electronic signature.**  
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/s/

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Russell Katz

8/14/02 03:51:08 PM

# EXHIBIT E

**SECURITIES AND EXCHANGE COMMISSION**  
**WASHINGTON, D.C. 20549**

**FORM 10-K**

(Mark one)

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d)  
OF THE SECURITIES EXCHANGE ACT OF 1934

**For the Fiscal Year Ended March 31, 2003**

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d)  
OF THE SECURITIES EXCHANGE ACT OF 1934

**For the transition period From \_\_\_\_\_ to \_\_\_\_\_**

**Commission File No. 1-5438**

**FOREST LABORATORIES, INC.**  
*(Exact name of registrant as specified in its charter)*

**Delaware**  
*(State or other jurisdiction of  
incorporation or organization)*

**11-1798614**  
*(I.R.S. Employer  
Identification Number)*

**909 Third Avenue**  
**New York, New York**  
*(Address of principal executive offices)*

**10022**  
*(Zip code)*

**(212) 421-7850**  
*(Registrant's telephone number, including area code)*

Securities registered pursuant to Section 12(b) of the act:

<b><u>Title of each class</u></b>	<b><u>Name of each exchange on which registered</u></b>
Common Stock, \$.10 par value	New York Stock Exchange
Rights, as adjusted, to purchase one eighth of one-hundredth share of Series A Junior Participating Preferred Stock, par value \$1.00 per share	New York Stock Exchange

Securities registered pursuant to Section 12(g) of the act:

S-2 VALUATION AND QUALIFYING ACCOUNTSEXHIBIT 13:QUARTERLY STOCK MARKET PRICES  
SELECTED FINANCIAL DATACONDENSED CONSOLIDATED FINANCIAL STATEMENTS:REPORT OF INDEPENDENT CERTIFIED PUBLIC ACCOUNTANTS  
BALANCE SHEETS  
STATEMENTS OF INCOME  
STATEMENTS OF COMPREHENSIVE INCOME  
STATEMENTS OF STOCKHOLDERS' EQUITY  
STATEMENTS OF CASH FLOW  
NOTES TO FINANCIAL STATEMENTSMANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL  
CONDITION AND RESULTS OF OPERATIONSEXHIBIT 23CERTIFICATIONS**PART I****ITEM 1. BUSINESS****General**

Forest Laboratories, Inc. and its subsidiaries (collectively, "Forest" or the "Company") develop, manufacture and sell both branded and generic forms of ethical drug products which require a physician's prescription, as well as non-prescription pharmaceutical products sold over-the-counter. Forest's most important United States products consist of branded ethical drug specialties marketed directly, or "detailed," to physicians by the Company's Forest Pharmaceuticals, Forest Therapeutics, Forest Healthcare and Forest Specialty Sales salesforces. The Company emphasizes detailing to physicians of those branded ethical drugs it believes have the most potential for growth, and the development and introduction of new products, including products developed in collaboration with licensing partners.

Forest's products include those developed by Forest and those acquired from other pharmaceutical companies and integrated into Forest's marketing and distribution systems. See "Recent Developments."

Forest is a Delaware corporation organized in 1956, and its principal executive offices are located at 909 Third Avenue, New York, New York 10022 (telephone number 212-421-7850).

**Recent Developments**

**Lexapro™:** In September 2002, Forest launched Lexapro (escitalopram oxalate), a single isomer version of Forest's Celexa™ (citalopram HBr) for the treatment of major depression, following approval of the product by the United States Food and Drug Administration (the "FDA") in August 2002. Citalopram is a racemic mixture with two mirror image molecules, the S- and R-isomers. The S-isomer of citalopram is the active isomer in terms of its contribution to citalopram's antidepressant effects, while the R-isomer does not

contribute to the antidepressant activity. With Lexapro, the R-isomer has been removed, leaving only the active S-isomer. Clinical trials demonstrate that Lexapro is a more potent selective serotonin reuptake inhibitor ("SSRI") than its parent compound, and confirm the antidepressant activity of Lexapro in all major clinical measures of depression. During fiscal 2003, sales of Lexapro were \$244,730,000. According to data published by IMS, an independent prescription audit firm, as of June 13, 2003, Lexapro achieved a 12.1% share of total prescriptions for antidepressants in the SSRI/SNRI category.

In November 2002, Forest submitted a supplemental New Drug Application ("sNDA") to the FDA seeking to expand the labeling of Lexapro to include generalized anxiety disorder ("GAD"), a disorder characterized by excessive anxiety and worry about every day events or activities for a period of 6 months or more. The submission was based upon three GAD studies involving Lexapro which demonstrated significantly greater improvement in anxiety symptoms relative to placebo. Forest hopes to have approval of the GAD indication around the end of calendar 2003 and begin marketing that indication in early calendar 2004. On May 1, 2003, the Company filed a second sNDA to further expand the labeling for Lexapro to include an indication for the treatment of panic disorder.

Lexapro was developed by Forest and H. Lundbeck A/S, a Danish pharmaceutical firm which licenses the United States marketing rights to this compound, as well as Celexa, to Forest.

**Celexa:** Sales of Celexa, an SSRI for the treatment of depression, were \$1,451,979,000 for the fiscal year ended March 31, 2003. Forest continues to sell Celexa, but discontinued the active promotion of the product at the time Lexapro was launched. According to data published by IMS, an independent prescription audit firm, as of June 13, 2003 Celexa declined from a peak share of 16.6% achieved in August 2002, to a 10.4% share of total prescriptions for antidepressants in the SSRI/SNRI category.

During fiscal 2003, the FDA granted Forest a six-month extension of the marketing exclusivity of Celexa based upon Forest's performance of clinical studies requested by the FDA to assess the safety, efficacy and pharmacokinetic profile of Celexa in pediatric populations. Based on this extension, Forest believes that the earliest an application for a generic form of the product could be submitted to the FDA would be January 2004, followed by a period of review by the FDA.

**Benicar™ Co-Promotion with Sankyo Pharma:** In December 2001, Forest entered into a co-promotion agreement with Sankyo Pharma ("Sankyo") for the co-promotion in the United States of Benicar (olmesartan medoxomil) an angiotensin receptor blocker discovered and developed by Sankyo for the treatment of hypertension. The NDA for Benicar was approved by the FDA in April 2002 and the product was commercially launched by the Sankyo and Forest salesforces in the United States in May 2002.

Pursuant to the co-promotion agreement with Sankyo, Forest and Sankyo will share in the detailing of the product to physicians, hospitals, managed care organizations and other institutional users of pharmaceutical products over a six-year period. Forest will receive co-promotion income based upon the relative contribution of the two companies to the co-promotion effort, and will receive residual payments following the end of the co-promotion period based on sales levels achieved.

In June 2003, Benicar HCT, a combination of Benicar and Hydrochlorothiazide, was approved by the FDA and will be marketed by Forest and Sankyo jointly under the co-promotion agreement.

**Memantine:** In August 2002, Forest submitted an NDA to the FDA to market memantine for the treatment of moderate to severe Alzheimer's disease. Memantine is a moderate-affinity, uncompetitive NMDA receptor antagonist that modulates the effects of glutamate - a neurotransmitter - found in the brain. Excessive levels of glutamate are hypothesized to contribute to the dysfunction and eventual death of brain cells observed in Alzheimer's disease. Forest believes that memantine's mechanism of action is distinct from drugs currently available to treat Alzheimer's disease. Forest obtained the exclusive rights to develop and market memantine in the United States by a license agreement with Merz + Co. GmbH of Germany, the originator of the product.

# EXHIBIT F





DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

NDA 21-323/S-003/S-007  
NDA 21-365/S-001/S-004

Forest Laboratories, Inc.  
Attention: Andrew Friedman, R.Ph.  
Manager, Regulatory Affairs  
Harborside Financial Center  
Plaza Three, Suite 602  
Jersey City, NJ 07311

Dear Mr. Friedman:

Please refer to your supplemental new drug applications dated November 26, 2002 (NDA 21-323/S-003 & 21-365/S-004), and February 6, 2003 (NDA 21-323/S-007 & 21-365/S-001), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lexapro (escitalopram oxalate) Tablets (NDA 21-323) and Lexapro (escitalopram oxalate) Oral Solution (NDA 21-365).

We acknowledge receipt of your submissions dated October 20, October 27, December 4, and December 11, 2003.

Your submission of October 20, 2003, constituted a complete response to our September 26, 2003 action letter for supplemental applications 21-323/S-003 & 21-365/S-004, and your submission of December 11, 2003, constituted a complete response to our November 25, 2003 action letter for supplemental applications 21-323/S-007 & 21-365/S-001.

These supplements provide for the following revisions to labeling:

Under supplemental applications 21-323/S-007 & 21-365/S-001: efficacy study reports from Studies 99001 & 99003 as additional trials supporting the efficacy of escitalopram in the treatment of major depressive disorder.

Under supplemental applications 21-323/S-003 & 21-365/S-004: treatment of generalized anxiety disorder.

We have completed the review of these applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the enclosed labeling text. Accordingly, these applications are approved effective on the date of this letter.

We note your agreement to the attached labeling in conference calls dated December 11, and 16, 2003, between the Agency and representatives from Forest.

NDA 21-323/S-003/S-007 & NDA 21-365/S-001/S-004

Page 2

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplements 21-323/S-003/S-007 & NDA 21-365/S-001/S-004." Approval of these submissions by FDA is not required before the labeling is used.

Additionally, we are requesting that you submit a "Prior Approval" supplemental new drug application to incorporate a new subsection under **ADVERSE REACTIONS** entitled **Events Reported Subsequent to the Marketing of Escitalopram**. This section should include all of the adverse events reported since marketing of escitalopram and not reported during the premarketing of escitalopram and the postmarketing of citalopram, i.e., these events would be postmarketing adverse events specific to escitalopram. This supplement should also contain the data to support your proposed additions to product labeling.

This supplement should be submitted within 60 days of this letter.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410  
FDA  
5600 Fishers Lane  
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Paul David, R.Ph., Senior Regulatory Project Manager, at (301) 594-5530.

Sincerely,

*{See appended electronic signature page}*

Russell Katz, M.D.  
Director  
Division of Neuropharmacological Drug Products  
Office of Drug Evaluation I  
Center for Drug Evaluation and Research

Attachment

-----  
**This is a representation of an electronic record that was signed electronically and  
this page is the manifestation of the electronic signature.**  
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/s/

-----  
Russell Katz  
12/18/03 09:31:43 AM

# **EXHIBIT G**

# SECURITIES AND EXCHANGE COMMISSION

## WASHINGTON, D.C. 20549

### FORM 10-K

(Mark one)

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d)  
OF THE SECURITIES EXCHANGE ACT OF 1934

**For the Fiscal Year Ended March 31, 2004**

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d)  
OF THE SECURITIES EXCHANGE ACT OF 1934

**For the transition period From \_\_\_\_\_ to \_\_\_\_\_**

**Commission File No. 1-5438**

**FOREST LABORATORIES, INC.**

*(Exact name of registrant as specified in its charter)*

**Delaware**  
*(State or other jurisdiction of  
incorporation or organization)*

**11-1798614**  
*(I.R.S. Employer  
Identification Number)*

**909 Third Avenue**  
**New York, New York**  
*(Address of principal executive offices)*

**10022**  
*(Zip code)*

**(212) 421-7850**  
*(Registrant's telephone number, including area code)*

Securities registered pursuant to Section 12(b) of the act:

<b><u>Title of each class</u></b>	<b><u>Name of each exchange on which registered</u></b>
Common Stock, \$.10 par value	New York Stock Exchange
Rights, as adjusted, to purchase one eighth of one-hundredth share of Series A Junior Participating Preferred Stock, par value \$1.00 per share	New York Stock Exchange

Securities registered pursuant to Section 12(g) of the act:

**Namenda™:** In October 2003, Namenda (memantine HCl) was approved for marketing and distribution by the United States Food and Drug Administration ("FDA") for the treatment of moderate to severe Alzheimer's disease. Initial stocking of Namenda began in December 2003 and the Company's salesforce began promotion of the product in March 2004. Sales of Namenda to March 31, 2004 were \$45,472,000. Namenda is a moderate-affinity, uncompetitive NMDA receptor antagonist that modulates the effects of glutamate - a neurotransmitter found in the brain. Excessive levels of glutamate are hypothesized to contribute to the dysfunction and eventual death of brain cells observed in Alzheimer's disease. Forest believes that Namenda's mechanism of action is distinct from drugs currently available to treat Alzheimer's disease. Forest obtained the exclusive rights to develop and market memantine in the United States by license agreement with Merz Pharma GmbH of Germany ("Merz"), the originator of the product.

During fiscal 2004, Forest announced the results of a six month placebo-controlled Phase III study of memantine in patients with mild to moderate Alzheimer's disease. In the study, patients who received memantine performed significantly better on both primary measures of cognition and global functioning than those given a placebo. Based on the results of this study, Forest expects to submit a supplemental NDA ("sNDA") to the FDA seeking approval for the mild to moderate Alzheimer's disease indication during the second half of calendar 2004.

In addition, Forest is conducting a Phase II program for the use of Namenda in neuropathic pain. While a 16 week Phase III clinical study for this indication completed during fiscal year 2004 failed to demonstrate statistical significance for the study's primary endpoints, an analysis of the study results demonstrated statistically significant weekly improvements in the assessments of nocturnal pain for the first 14 weeks. Based on the outcome of this Phase II program, Forest may choose to initiate additional Phase III trials required to submit an NDA for approval of Namenda for this indication.

**Lexapro®:** In September 2002, Forest launched Lexapro (escitalopram oxalate), a single isomer version of Forest's Celexa® (citalopram HBr) for the treatment of major depression, following approval of the product by the FDA in August 2002. Citalopram is a racemic mixture with two mirror image molecules, the S- and R-isomers. The S-isomer of citalopram is the active isomer in terms of its contribution to citalopram's antidepressant effects, while the R-isomer does not contribute to the antidepressant activity. With Lexapro, the R-isomer has been removed, leaving only the active S-isomer. Clinical trials demonstrate that Lexapro is a more potent selective serotonin reuptake inhibitor ("SSRI") than its parent compound, and confirm the antidepressant activity of Lexapro in all major clinical measures of depression. During fiscal 2004, sales of Lexapro were \$1,088,957,000. According to data published by IMS, an independent prescription audit firm, as of May 21, 2004, Lexapro achieved a 16.7% share of total prescriptions for antidepressants in the SSRI/SNRI category.

In December 2003, Lexapro received FDA approval of its sNDA for the treatment of generalized anxiety disorder ("GAD"), a disorder characterized by excessive anxiety and worry about every day events or activities for a period of 6 months or more. The approval was based upon three GAD studies involving Lexapro which demonstrated significantly greater improvement in anxiety symptoms relative to placebo. Forest began marketing Lexapro for the treatment of GAD in January 2004. An additional sNDA to further expand the labeling for Lexapro to include an indication for the treatment of social phobia, was filed on May 25, 2004.

Lexapro was developed by Forest and H. Lundbeck A/S, a Danish pharmaceutical firm which licenses the exclusive United States marketing rights to this compound, as well as Celexa, to Forest.

**Celexa:** Sales of Celexa, an SSRI for the treatment of depression, were \$1,087,281,000 for the fiscal year ended March 31, 2004. Forest continues to sell Celexa, but discontinued the active promotion of the product at the time Lexapro was launched. According to data published by IMS, an independent prescription audit firm, as of May 21, 2004 Celexa declined from a peak share of 17.5% achieved in August 2002, to an 8.7% share of total prescriptions for antidepressants in the SSRI/SNRI category.

Forest believes that one or more applications by generic distributors to introduce generic forms of

# EXHIBIT H

10-K 1 forest10k2005.htm FOREST LABORATORIES, INC. 10-K MARCH 31, 2005

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

**FORM 10-K**

(Mark one)

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d)  
OF THE SECURITIES EXCHANGE ACT OF 1934

**For the Fiscal Year Ended March 31, 2005**

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d)  
OF THE SECURITIES EXCHANGE ACT OF 1934

**For the transition period From \_\_\_\_\_ to \_\_\_\_\_**

**Commission File No. 1-5438**

**FOREST LABORATORIES, INC.**  
*(Exact name of registrant as specified in its charter)*

**Delaware**  
*(State or other jurisdiction of  
incorporation or organization)*

**11-1798614**  
*(I.R.S. Employer  
Identification Number)*

**909 Third Avenue  
New York, New York**  
*(Address of principal executive offices)*

**10022**  
*(Zip code)*

**(212) 421-7850**  
*(Registrant's telephone number, including area code)*

Securities registered pursuant to Section 12(b) of the act:

**Title of each class**

Common Stock, \$.10 par value

**Name of each exchange  
on which registered**

New York Stock Exchange

Securities registered pursuant to Section 12(g) of the act:



CONDENSED CONSOLIDATED FINANCIAL STATEMENTS:

MANAGEMENT'S REPORT ON INTERNAL CONTROL OVER FINANCIAL REPORTING  
REPORTS OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM  
BALANCE SHEETS  
STATEMENTS OF INCOME  
STATEMENTS OF COMPREHENSIVE INCOME  
STATEMENTS OF STOCKHOLDERS' EQUITY  
STATEMENTS OF CASH FLOW  
NOTES TO FINANCIAL STATEMENTS

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL  
CONDITION AND RESULTS OF OPERATIONS

EXHIBIT 10.7  
EXHIBIT 13  
EXHIBIT 23  
EXHIBIT 31.1  
EXHIBIT 31.2  
EXHIBIT 32.1  
EXHIBIT 32.2

## **PART I**

### **ITEM 1. BUSINESS**

#### **General**

Forest Laboratories, Inc. and its subsidiaries develop, manufacture and sell both branded and generic forms of ethical drug products which require a physician's prescription, as well as non-prescription pharmaceutical products sold over-the-counter. Our most important United States products consist of branded ethical drug specialties marketed directly, or "detailed," to physicians by our Forest Pharmaceuticals, Forest Therapeutics, Forest Healthcare, Forest Ethicare and Forest Specialty Sales salesforces. We emphasize detailing to physicians of those branded ethical drugs which we believe have the most potential for growth, and the development and introduction of new products, including products developed in collaboration with licensing partners.

Our products include those developed by us and those acquired from other pharmaceutical companies and integrated into our marketing and distribution systems.

We are a Delaware corporation organized in 1956, and our principal executive offices are located at 909 Third Avenue, New York, New York 10022 (telephone number 212-421-7850). Our corporate website address is <http://www.frx.com>. We make all electronic filings with the Securities and Exchange Commission (or SEC), including Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those Reports available on our corporate website free of charge as soon as practicable after filing with or furnishing to the SEC.

#### **Recent Developments**

**Lexapro®:** In September 2002, we launched Lexapro (escitalopram oxalate), a single isomer version of Celexa® (citalopram HBr) for the treatment of major depression, following approval of the product

<http://www.sec.gov/Archives/edgar/data/38074/000003807405000018/forest10k2005.htm>

08/23/07

by the FDA in August 2002. Citalopram is a racemic mixture with two mirror image molecules, the S- and R-isomers. The S-isomer of citalopram is the active isomer in terms of its contribution to citalopram's antidepressant effects, while the R-isomer does not contribute to the antidepressant activity. With Lexapro, the R-isomer has been removed, leaving only the active S-isomer. Clinical trials demonstrate that Lexapro is a more potent selective serotonin reuptake inhibitor (or SSRI) than its parent compound, and confirm the antidepressant activity of Lexapro in all major clinical measures of depression. During fiscal 2005, sales of Lexapro were \$1,605,296,000. According to data published by IMS, an independent prescription audit firm, as of April 30, 2005, Lexapro achieved a 19.9% share of total prescriptions for antidepressants in the SSRI/SNRI category.

In December 2003, Lexapro received FDA approval for the treatment of generalized anxiety disorder (or GAD), a disorder characterized by excessive anxiety and worry about every day events or activities for a period of 6 months or more. The approval was based upon three GAD studies involving Lexapro which demonstrated significantly greater improvement in anxiety symptoms relative to placebo. Forest began marketing Lexapro for the treatment of GAD in January 2004.

During fiscal 2005, we received a "non-approvable letter" from the United States Food and Drug Administration (or FDA) with respect to a supplemental New Drug Application (or sNDA) submission by us for the panic disorder indication. The non-approvable response was confirmed by the FDA after our submission of additional data in response to an initial FDA non-approvable letter. In addition, during fiscal 2005, we received a "non-approvable letter" from the FDA with respect to our sNDA submission for social anxiety disorder. While indicating that data from one of the two required pivotal studies supported the application, the FDA raised questions related to the reliability of patient data at one center in the second trial. We are reviewing the FDA's analysis and expect to determine the next stages, which may include additional discussions with the FDA pertaining to the excluded study center or the conduct of an additional pivotal trial, during the first half of fiscal 2006.

Lexapro was developed by us and H. Lundbeck A/S (or Lundbeck), a Danish pharmaceutical firm which licenses to us the exclusive United States marketing rights to this compound, as well as Celexa.

**Celexa:** During fiscal 2005, numerous applications by generic distributors to distribute generic forms of Celexa, our SSRI for the treatment of depression, were approved by the FDA and the product now faces competition from numerous generic sources. At the time of such generic market entry, we launched our own generic version of the product and the branded product is no longer actively promoted by our salesforce. Sales of Celexa were \$653,450,000 during fiscal 2005, but only \$6,197,000 during the fourth quarter as the full effect of generic competition was realized. Sales of our generic version of Celexa amounted to \$4,564,000 for fiscal 2005.

**Namenda®:** In October 2003, Namenda (memantine HCl) was approved for marketing and distribution by the FDA for the treatment of moderate to severe Alzheimer's disease. Initial stocking of Namenda occurred in December 2003 and our salesforce began product promotion in March 2004. Namenda is a moderate-affinity, uncompetitive NMDA receptor antagonist that modulates the effects of glutamate - a neurotransmitter found in the brain. Excessive levels of glutamate are hypothesized to contribute to the dysfunction and eventual death of brain cells observed in Alzheimer's disease. We believe that Namenda's mechanism of action is distinct from other drugs currently available to treat Alzheimer's disease. We obtained the exclusive rights to develop and market memantine in the United States by license agreement with Merz Pharma GmbH of Germany, the originator of the product.

Namenda achieved sales of \$332,707,000 during our 2005 fiscal year. During fiscal 2005, the FDA accepted our sNDA to expand the indication of Namenda to include treatment of mild Alzheimer's disease and under existing FDA procedures, we should receive an initial action letter from the FDA by the third calendar quarter of 2005. The sNDA submission includes data from three studies: two double-blind, placebo-controlled studies of Namenda as monotherapy in mild to moderate Alzheimer's disease and one double-blind, placebo-controlled study of Namenda administered to patients already taking an acetylcholinesterase inhibitor. Data

# EXHIBIT I

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

**FORM 10-K**

(Mark one)

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d)  
OF THE SECURITIES EXCHANGE ACT OF 1934

**For the Fiscal Year Ended March 31, 2006**

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d)  
OF THE SECURITIES EXCHANGE ACT OF 1934

**For the transition period from \_\_\_\_\_ to \_\_\_\_\_**

**Commission File No. 1-5438**

**FOREST LABORATORIES, INC.**

*(Exact name of registrant as specified in its charter)*

**Delaware**  
*(State or other jurisdiction of  
incorporation or organization)*

**11-1798614**  
*(I.R.S. Employer  
Identification Number)*

**909 Third Avenue  
New York, New York**  
*(Address of principal executive offices)*

**10022**  
*(Zip code)*

**(212) 421-7850**  
*(Registrant's telephone number, including area code)*

Securities registered pursuant to Section 12(b) of the act:

<b><u>Title of each class</u></b>	<b><u>Name of each exchange on which registered</u></b>
Common Stock, \$.10 par value	New York Stock Exchange

Securities registered pursuant to Section 12(g) of the act:

None

trials within the next two to three years. We paid Richter an upfront payment and will pay milestone payments based upon the achievement of development objectives in addition to royalties. We will have exclusive marketing rights in North America while Richter will retain exclusive rights in Europe and countries comprising the former Soviet Union. The two companies will share rights in other countries.

**Lexapro®:** In September 2002, we launched Lexapro (escitalopram oxalate), a single isomer version of Celexa® (citalopram HBr) for the treatment of major depression, following approval of the product by the FDA in August 2002. Citalopram is a racemic mixture with two mirror image molecules, the S- and R-isomers. The S-isomer of citalopram is the active isomer in terms of its contribution to citalopram's antidepressant effects, while the R-isomer does not contribute to the antidepressant activity. With Lexapro, the R-isomer has been removed, leaving only the active S-isomer. Clinical trials demonstrate that Lexapro is a more potent selective serotonin reuptake inhibitor (or SSRI) than its parent compound, and confirm the antidepressant activity of Lexapro in all major clinical measures of depression. During fiscal 2006, sales of Lexapro were \$1,873,255,000. According to data published by IMS, an independent prescription audit firm, as of April 30, 2006, Lexapro achieved a 20.1% share of total prescriptions for antidepressants in the SSRI/SNRI category.

In December 2003, Lexapro received FDA approval for the treatment of generalized anxiety disorder (or GAD), a disorder characterized by excessive anxiety and worry about every day events or activities for a period of 6 months or more. The approval was based upon three GAD studies involving Lexapro which demonstrated significantly greater improvement in anxiety symptoms relative to placebo. Forest began marketing Lexapro for the treatment of GAD in January 2004.

During fiscal 2005, we received a "non-approvable letter" from the FDA with respect to a supplemental New Drug Application (or sNDA) submission by us for the panic disorder indication. The non-approvable response was confirmed by the FDA after our submission of additional data in response to an initial FDA non-approvable letter. In addition, during fiscal 2005, we received a "non-approvable letter" from the FDA with respect to our sNDA submission for social anxiety disorder.

Lexapro was developed by us and H. Lundbeck A/S (or Lundbeck), a Danish pharmaceutical firm which licenses to us the exclusive United States marketing rights to this compound, as well as Celexa.

Lexapro is covered by a composition of matter patent which expires March 14, 2012, giving effect to six months of additional exclusivity granted as a result of a pediatric study which we performed and to an 828 day patent term extension granted by the US Patent and Trademark Office in March 2006. Information concerning patent infringement litigation brought by us and Lundbeck in connection with filings seeking regulatory approval for generic versions of Lexapro is set forth below at Item 3. Legal Proceedings. In addition, we have received notice of another submission for regulatory approval for a generic version of Lexapro which challenges our patents. We intend to fully enforce our patent rights as and when appropriate.

**Celexa:** During fiscal 2005, numerous applications by generic distributors to distribute generic forms of Celexa, our SSRI for the treatment of depression, were approved by the FDA and the product now faces competition from numerous generic sources. At the time of such generic market entry, we launched our own generic version of the product and the branded product is no longer actively promoted by our salesforce. Sales of our branded and generic versions of Celexa amounted to \$19,006,000 for fiscal 2006.

**Namenda®:** In October 2003, Namenda (memantine HCl) was approved for marketing and distribution by the FDA for the treatment of moderate to severe Alzheimer's disease. Initial stocking of Namenda occurred in December 2003 and our salesforce began product promotion in March 2004. Namenda is a moderate-affinity, uncompetitive NMDA receptor antagonist that modulates the effects of glutamate - a neurotransmitter found in the brain. Excessive glutamergic activity is hypothesized to contribute to the dysfunction and eventual death of brain cells observed in Alzheimer's disease. We believe that Namenda's mechanism of action is distinct from other drugs currently available to treat Alzheimer's disease. We obtained the exclusive rights to develop and market memantine in the United States by license agreement with Merz

# EXHIBIT J

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

**FORM 10-K**

(Mark one)

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d)  
OF THE SECURITIES EXCHANGE ACT OF 1934

**For the Fiscal Year Ended March 31, 2007**

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d)  
OF THE SECURITIES EXCHANGE ACT OF 1934

**For the transition period from \_\_\_\_\_ to \_\_\_\_\_**

**Commission File No. 1-5438**

**FOREST LABORATORIES, INC.**  
*(Exact name of registrant as specified in its charter)*

**Delaware**  
*(State or other jurisdiction of  
incorporation or organization)*

**11-1798614**  
*(I.R.S. Employer  
Identification Number)*

**909 Third Avenue  
New York, New York**  
*(Address of principal executive offices)*

**10022**  
*(Zip code)*

**(212) 421-7850**  
*(Registrant's telephone number, including area code)*

Securities registered pursuant to Section 12(b) of the Act:

<b><u>Title of each class</u></b>	<b><u>Name of each exchange on which registered</u></b>
Common Stock, \$.10 par value	New York Stock Exchange

Securities registered pursuant to Section 12(g) of the act:

None



The second new collaboration will focus upon a group of novel compounds that target metabotropic glutamate receptors (mGLUR1/5). mGLUR1/5 antagonists represent novel potential agents for the treatment of anxiety, depression and other CNS conditions. Richter and Forest intend to advance promising leads to clinical trials within the next two to three years. We paid Richter an upfront payment and will pay milestone payments based upon the achievement of development objectives in addition to royalties. We will have exclusive marketing rights in North America while Richter will retain exclusive rights in Europe and countries comprising the former Soviet Union. The two companies will share rights in other countries.

**Lexapro®:** In September 2002, we launched Lexapro (escitalopram oxalate), a single isomer version of Celexa® (citalopram HBr) for the treatment of major depression, following approval of the product by the FDA in August 2002. Citalopram is a racemic mixture with two mirror image molecules, the S- and R-isomers. The S-isomer of citalopram is the active isomer in terms of its contribution to citalopram's antidepressant effects, while the R-isomer does not contribute to the antidepressant activity. With Lexapro, the R-isomer has been removed, leaving only the active S-isomer. Clinical trials demonstrate that Lexapro is a more potent selective serotonin reuptake inhibitor (or SSRI) than its parent compound, and confirm the antidepressant activity of Lexapro in all major clinical measures of depression. During fiscal 2007, sales of Lexapro were \$2,105,990,000. According to data published by IMS, an independent prescription audit firm, as of April 30, 2007, Lexapro achieved an 18.5% share of total prescriptions for antidepressants in the SSRI/SNRI category.

In December 2003, Lexapro received FDA approval for the treatment of generalized anxiety disorder (or GAD), a disorder characterized by excessive anxiety and worry about every day events or activities for a period of 6 months or more. The approval was based upon three GAD studies involving Lexapro which demonstrated significantly greater improvement in anxiety symptoms relative to placebo. Forest began marketing Lexapro for the treatment of GAD in January 2004.

Lexapro was developed by us and H. Lundbeck A/S (or Lundbeck), a Danish pharmaceutical firm which licenses to us the exclusive United States marketing rights to this compound, as well as Celexa.

Lexapro is covered by a composition of matter patent which expires March 14, 2012, inclusive of additional exclusivity granted as a result of a pediatric study which we performed and to an 828 day patent term extension granted by the U.S. Patent and Trademark Office in March 2006. In July 2006, the U.S. District Court for the District of Delaware determined that our composition of matter patent is both valid and enforceable against a generic product proposed to be sold by Teva Pharmaceuticals. Information concerning this case and other patent infringement litigation brought by us and Lundbeck in connection with filings seeking regulatory approval for generic versions of Lexapro is set forth below at Item 3. Legal Proceedings. We intend to fully enforce our patent rights.

**Namenda®:** In October 2003, Namenda (memantine HC1) was approved for marketing and distribution by the FDA for the treatment of moderate to severe Alzheimer's disease. Initial stocking of Namenda occurred in December 2003 and our salesforce began product promotion in March 2004. Namenda is a moderate-affinity, uncompetitive NMDA receptor antagonist that modulates the effects of glutamate - a neurotransmitter found in the brain. Excessive levels of glutamate are hypothesized to contribute to the dysfunction and eventual death of brain cells observed in Alzheimer's disease. We believe that Namenda's mechanism of action is distinct from other drugs currently available to treat Alzheimer's disease. We obtained the exclusive rights to develop and market memantine in the United States by license agreement with Merz Pharma GmbH of Germany (or Merz), the originator of the product.

Namenda achieved sales of \$660,295,000 during our 2007 fiscal year and, according to data published by IMS, an independent prescription audit firm, as of April 30, 2007, Namenda achieved a 33.0% share of total prescriptions in the Alzheimer's market. During fiscal 2005, the FDA accepted for review our sNDA to expand the indication of Namenda to include treatment of mild Alzheimer's disease. In July 2005, we received a "non-approvable" letter from the FDA with respect to the mild Alzheimer's disease indication. In May 2006, the FDA reaffirmed the non-approvable status of Namenda in mild patients. Namenda is covered by



# **EXHIBIT K**

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lexipro

Search

Advanced Search

Preferences

New! View and manage your web history

Web Results 1 - 10 of about 54,000 for **lexipro**. (0.05 seconds)

### Lexapro - Official Site

www.Lexapro.com Get the Facts About Lexapro & Find Useful Depression Resources

Sponsored Link

### Sponsored Links

**CanadaPharmacy.com**

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Did you mean: **lexapro**

### Lexipro

Lexapro is a drug licensed for the treatment of depression and generalized anxiety disorder. This eMedTV Web page covers how the drug works, ...  
depression.emedtv.com/lexapro/lexipro.html - 20k - [Cached](#) - [Similar pages](#)

### LEXIPRO - Drugs.com

Hi. I'm new here so i'm not sure if I'm doing this in the right place. I wanted some advice. I've been on only .5mg of **lexipro** for about 8 months and.

www.drugs.com/forum/featured-conditions/lexipro-33168.html - 45k -

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#### new on lexipro - Drugs.com

ive read everyones comments about **lexipro**. i used it a few months ago and was fine, though i came off them too early and have just been put back on.

www.drugs.com/forum/drug-information/new-lexipro-38861.html - 38k -

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### Lexipro- side effects - HealingWell.com Forum

**Lexipro-** side effects, Forum Quick Jump. Select A Location, \*\*\*\*\* Top of the Forum \*\*\*\*\* ,  
==== General Information ====, Announcements, Frequently Asked ...

www.healingwell.com/community/default.aspx?f=19&m=727673 - 92k -

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#### Lexipro-when do the side effects abate? - HealingWell.com Forum

I have been on **Lexipro** for over a year now and I havent had any side effects or problems with it. What dosage are you on? I would give it another week or so ...

www.healingwell.com/community/default.aspx?f=10&m=433565 - 37k -

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### dropping the Effexor/Lexapro weight gain - Weight Loss

I tried others, including **Lexipro**. I literally went to bed weighing 145 and ... Thats when a new Dr. suggested the **Lexipro**; when I commented about weight ...

www.medhelp.org/forums/WeightLoss/messages/573.html - 263k - [Cached](#) - [Similar pages](#)

### MyTherapy Discussion Forums - Lexipro

Hello...my doctor just put me on **Lexipro** for depression. Does anybody know the side effects of this drug...or any information at all. ...

www.mytherapy.com/discussion/topic.asp?TOPIC\_ID=3688 - 84k - [Cached](#) - [Similar pages](#)

### Coming Off Of Lexipro

Coming Off Of **Lexipro** Health: Body, Mind and Spirit.

www.enotalone.com/forum/showthread.php?t=126518 - [Similar pages](#)

### Yahoo! Answers - Tell me about Lexipro?

4 answers - I recently started taking **lexipro**... I've been on it before but I'm getting wicked

<http://www.google.com/search?hl=en&q=lexipro>

08/28/07

side effects. It's only 10mg.... Is anyone else suffering ...  
ph.answers.yahoo.com/question/index?qid=20070711045213AA3ahHO - 81k -  
[Cached](#) - [Similar pages](#)

**Pharmacy: Lexipro (Anxiety/Dep. Medication)**

Dear Julie, Thank you for your question. It may well be that your tiredness is a result of this drug (between 1 in 10 and 1 in 100 people will experience ...  
en.allexperts.com/q/Pharmacy-1407/Lexipro-Anxiety-Dep-Medication.htm - 20k -  
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### Everyone Needs Therapy: Grandchildren, Gilmore, and Lexipro

I've seen many patients on **Lexipro** with absolutely NO problems with libido (sexual drive) and no weight gain. So shut-up, Paris. And Gilmore Girls writers? ...

everyoneneedstherapy.blogspot.com/2006/11/grandchildren-gilmore-and-lexipro.html - 84k - [Cached](#) - [Similar pages](#)

### Myoclonus, Lexipro, and Depakote - BrainTalk Communities

Two years ago, my shrink put me on **Lexipro** for severe depression. I noticed that after I had been taking it for about a month, that I would get uncontrolled ...

brain.hastypastry.net/forums/showthread.php?p=110751 - 65k - [Cached](#) - [Similar pages](#)

### Yahoo! Answers - What are some side effects of lexipro?

5 answers - Yahoo! Answers - what are some side effects of **lexipro**?

answers.yahoo.com/question/index?qid=20060630173656AAZFo9J - 100k - [Cached](#) - [Similar pages](#)

### LexiPro - Lexicon for Hebrew Speakers > PilotYid Jewish Hebrew ...

Author: Top Technology License: Commercial Download **LexiPro** - Lexicon for Hebrew Speakers · <- Back To Jewish Palm Software Collection ...

www.pilotyid.com/jewish-hebrew-palm.php?LexiPro---Lexicon-for-Hebrew-Speakers&appld=418 - 8k - [Cached](#) - [Similar pages](#)

### Lexipro | Anti Depressant Therapies | Prozac | Paxil | Pharmacy

**Lexipro**, Anti Depressant Therapies, Prozac, Paxil, Pharmacy.

www.antiagingmatrix.com/bio\_antidepressant.php - 109k - [Cached](#) - [Similar pages](#)

### withdrawal - booze, lexipro, dignity

And I just stopped taking **Lexipro** prescribed for my severe depression and debilitating anxiety disorder that landed me in the nut-house for a week last ...

www.dr-bob.org/babble/subs/20050602/messages/524596.html - 11k - [Cached](#) - [Similar pages](#)

### Lexipro side effects

I have been taking **lexipro** for about a month. I'm not sure if its really working or not. It makes me feel like i've done acid stayed up all night and its ...

www.dr-bob.org/babble/psycho/20030407/messages/226386.html - 8k - [Cached](#) - [Similar pages](#)

### The Shambling Darkness Project: Pushing The Lexipro Envelope

Pushing The **Lexipro** Envelope. Mr. Snodgrass: "So what, this Flickr thing costs like twenty five bucks a year or something." ...

shamblingdarkness.blogspot.com/2007/07/pushing-lexipro-envelope.html - 77k - [Cached](#) - [Similar pages](#)

### Lexipro LLC, Professional Language Services

Lexiprollc provides translation, interpretation, localization including software and website localization, voice over and bilingual staffing in more than 60 ...

www.lexiprollc.com/ - 4k - [Cached](#) - [Similar pages](#)

### Male Sexual side affects POST lexipro use

I was curious if anyone has had male sexual > side effects AFTER quitting **lexipro**? > I had a standard side effect while taking > it, it took much longer to ...

http://www.google.com/search?q=lexipro&hl=en&start=10&sa=N

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### Tell me about **Lexipro**? - Yahoo!7 Answers

"Tell me about **Lexipro**?" - Find the answer to this question and millions more on Yahoo!7 Answers.

answers.yahoo.com.au/question/index?qid=20070711045213AA3ahHO - 81k -

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### Is the medication **lexipro** addictive? What have your experiences ...

"Is the medication **lexipro** addictive? What have your experiences with it been like?" - Find the answer to this question and millions more on Yahoo!7 ...

answers.yahoo.com.au/question/index?qid=20070417142001AAjol0W -

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### Xanax And **Lexipro**

you xanax and **lexipro** I have done nothing but I thank God for about 8 months now by phpwind.net - Bluelight Been on anti depressant xanax and **lexipro** kinds ...

ci.pleasant-hill.ia.us/autoindex/?drug=/b/xanax/and\_**lexipro**.html - 16k -

[Cached](#) - [Similar pages](#)

### **Lexipro** Buspar Zoloft

As well as depression, Buspirone · · - HealthBoards.com Message Boards and what **lexipro** buspar zoloft forte anxiety child effects brain long term effects ...

ci.pleasant-hill.ia.us/autoindex/?drug=/b/zoloft/**lexipro**\_buspar.html - 16k -

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### LoCarbDiner Bulletin Board - Dieting Stories>hormones and **Lexipro** ...

Has anyone on **Lexipro** and hormones had success with this diet? ... I'm on **lexipro** but not hormones - I haven't really noticed an impact on my appetite. ...

www.locarbdiner.com/cgi-bin/EZBulletin/bbtopic.cgi?

SUID=X309674&&topic=hormones\_and\_**Lexipro**\_antid... - 9k - [Cached](#) - [Similar pages](#)

### Undetectable at 12 Weeks and a question about **Lexipro** - Hepatitis

Interactive medical question and answer format about all aspects of acne treatments.

www.medhelp.org/forums/Hepatitis/messages/35933.html - 36k - [Cached](#) - [Similar pages](#)

### FreeTrainers Forums - **Lexipro** side effects

I saw my internist and he prescribed **Lexipro**..I have been on it one week and tolerated it OK with the exception of being woken at 2:30am with my pulse ...

www.freetrainers.com/FT/jsp/Message.jsp?f\_ix=16&t\_ix=548 - 23k - [Cached](#) - [Similar pages](#)

### Yahoo! Answers - **Lexipro** Side Affect?

2 answers - I have been taking **lexipro** for some time and I find that if I lower the dosage or stop the medication gradually as indicated I suffer from ...

answers.yahoo.com/question/index?qid=20061107105241AAVgoyX - 64k -

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### MySpace.com - **Lexipro** - 33 - Female - The Drunken Clam, US - www ...

MySpace profile for **Lexipro** with pictures, videos, personal blog, interests, information about me and more.

profile.myspace.com/index.cfm?fuseaction=user.viewprofile&friendid=594051 - 153k -

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At **Lexipro**, LLC, languages are our passion. Thanks to our network of professional certified language specialists and project managers we assist companies ...

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### Largest supply of adipelex and **lexipro** & cheap adipelex on line cheap ...

Adipelex And **Lexipro** and blueglobus adipelex. adipelex and **lexipro** - Fill out the order form and a US physician will review your order free of charge.  
www.adipelex-for-less.com/adipelex-and-**lexipro**.htm - [Similar pages](#)

### Cheapest **lexipro** versus celexa

This item is made in favor of our readers who have already acquired a basic understanding of the issue of net meds. For them the study bellow is supposed to ...

www.tophar.com/21072.html - 18k - [Cached](#) - [Similar pages](#)

### ObesityHelp.com: Making the Journey Together Welcome, Guest ...

I too tried **Lexipro** for about a week, the entire time I clenched my teeth ... My sister (who has NEVER had a weight problem, tried **Lexipro** for a few months ...

www.obesityhelp.com/morbidobesity/information/question.php?N=O1140790611 -

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### livre **lexipro** anglais des assistants, dictionnaires de langue ...- [ [Translate this page](#) ]

**Lexipro** anglais des assistants. Auteur(s) : MADOYAN Date de parution: 09-1999 Langue :

FRANÇAIS Etat : Disponible chez l'éditeur (délai de livraison : 3 ...

www.lavoisier.fr/notice/frHROKO2RG63MKS3.html - 14k - [Cached](#) - [Similar pages](#)

### Gluten-Free Celiac Disease Forum at Celiac.com (Home) > Weight ...

Question is: Could absorbing issues contribute to the weight gain, or could the **lexipro** add to this individually or in conjunction? ...

www.glutenfreeforum.com/lofiversion/index.php/t11545.html - 25k - [Cached](#) - [Similar pages](#)

### The Leukemia & Lymphoma Society BBS - Reply to Topic

I was put on Celexa for a couple of years after chemo and then I was switched to **Lexipro**.

Those did not help.....I'm actually being weaned off the ...

ubb-lls.leukemia-lymphoma.org/cgi-bin/ubbcbgi/postings.cgi?

action=reply&forum=Life+After+Cancer&nu... - 10k - [Cached](#) - [Similar pages](#)

### LEXIQUE\_UT- [ [Translate this page](#) ]

Dans le domaine de l'urbanisme, de l'aménagement de l'habitat & de la politique de la Ville les abréviations et les sigles sont légion. ...

urbanistesdesterritoires.com/texte/fichiers/LEXIQUE\_ville.htm - 155k -

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### Yahoo! Answers - Attention actors/artists with Bipolar Disorder!?

my daughter has bipolar disorder and she currently takes two meds, **Lexipro** and another one. she takes the **lexipro** for the depression and depekote for the ...

sg.answers.yahoo.com/question/index?qid=20070825170109AA3oRbE - 55k -

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### Print: plndI-gdl-proc-2003-mohamadkha-2@1182005674 - agriKnow

**lexipro** order [url=http://ubspharm.blog.drecom.jp/archive/3]**lexipro** order[url] wellbutrin

[url=http://ubspharm.blog.drecom.jp/archive/10]wellbutrin[url] ...

pln.penanglib.gov.my/print.php?id=plndI-gdl-proc-2003-mohamadkha-2@1182005674 - 13k

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ADHD Message Boards: lexapro and ritalin

I just so happen to be on 10 mg of **lexipro** and 20mg of ritalin LA. ... I find the **lexipro** to work well. I was on paxil before and the **lexipro** works better ...

[www.adhdnews.com/forum/forum\\_posts.asp?TID=5565&PN=1](http://www.adhdnews.com/forum/forum_posts.asp?TID=5565&PN=1) - 35k -

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# EXHIBIT L



## Lexipro

Were you looking for information about **Lexapro**? *Lexipro* is a common misspelling of Lexapro.

Lexapro® (escitalopram oxalate) is a prescription drug that is commonly used for treating **depression** and **generalized anxiety disorder**. The medicine works by helping to block the reuptake of a chemical in the brain called serotonin. A few common **Lexapro side effects** include nausea, **insomnia**, and headache. Some of the conditions you should let your healthcare provider know about before you take Lexapro include **diabetes**, **seizures** or **epilepsy**, and **bipolar disorder (manic-depression)** or a family history of **bipolar disorder**.

(Click **Lexapro** for more detailed information about other uses of Lexapro, as well as the medicine's potential side effects and general dosing guidelines.)

Last reviewed/updated February 18, 2007

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